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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,362	06/22/2000	Dirk Jager	LUD-5615.1-CIP-(10006411)	8875

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EXAMINER	
NICKOL, GARY B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/602,362	JAGER ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 81-157 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 81-157 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 81-157 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 81-88, 90-100, 106-107, 135-136, 157, drawn to isolated nucleic acid molecules encoding a cancer antigen, expression vectors, and host cells comprising said nucleic acid molecules, classified in class 536, subclass 23.5; class 435, subclass 320.1, 325.

II. Claims 89, 101-105, 113, 132-134, drawn to an isolated cancer-associated antigen and immunogenic compositions thereof, classified in class 530, subclass 300,350; class 514, subclass 2.

III. Claims 108-112, drawn to a vaccine or composition of matter useful in treating a cancerous condition comprising an isolated eukaryotic cell line, classified in class 424, subclass 93.21.

IV. Claims 114-115, drawn to an isolated antibody specific for a cancer antigen, classified in Class 530, subclass 387.7.

V. Claims 116, 141-144, drawn to a method for screening for cancer comprising contacting a sample with a nucleic acid molecule which hybridizes to all or part of the molecule encoded by SEQ ID Nos: 15, 22, or 26 and or assaying for expression of said SEQ ID Nos:, classified in class 435, subclass 6; class 436, subclass 64.

VI. Claim 117, drawn to a method of screening for cancer in a sample, comprising contacting said sample with an isolated antibody, and determining binding of said antibody to a target as an indicator of cancer, classified in class 455, subclass 7.23.

VII. Claim 118, drawn to a method for diagnosing cancer comprising contacting an immune reactive cell containing sample to a cell line with transfected nucleic acids, and determining interaction of said cell line with said immunoreactive cells, said interaction being indicative of cancer, classified in class 436, subclass 64, 503.

VIII. Claims 119-124,145-150, as specifically drawn to a method for monitoring a cancerous condition in a patient comprising assaying a protein encoded by SEQ ID Nos: 15, 22, or 26 or a peptide derived from said protein, classified in class 424, subclass 9.1.

IX. Claims 119-121,129, 145-147, 154, as specifically drawn to a method for monitoring a cancerous condition in a patient comprising assaying for shed protein, classified in class 424, subclass 9.1.

X. Claims 119-121, 145-147, as specifically drawn to a method for monitoring a cancerous condition in a patient comprising assaying cytolytic T cells specific for cancer antigens encoded by SEQ ID Nos: 15, 22, or 26 and a MHC molecule with which it non-covalently complexes to, classified in class 424, subclass 9.1; class 435, subclass 372.3.

XI. Claims 119-120,130, 145-146, 155, as specifically drawn to a method for monitoring a cancerous condition in a patient comprising assaying for antibodies specific for a cancer antigen, classified in class 424, subclass 9.1; class 436, subclass 506.

XII. Claims 119-121, 125-128, 145-147, 151-153 as specifically drawn to a method for monitoring a cancerous condition in a patient comprising assaying the nucleic acids of SEQ ID Nos: 15, 22, or 26, classified in class 424, subclass 9.1; class 435, subclass 6.

XIII. Claims 131,156, drawn to a method for diagnosing a cancerous condition comprising assaying for an immunoreactive cell specific for a peptide derived from a protein encoded by SEQ ID Nos: 15, 22, or 26, complexed to an MHC molecule, classified in class 436, subclass 64.

XIV. Claims 137-140, drawn to a method for screening for the presence of cancer comprising assaying a sample from a patient for the presence of antibodies that are specific to a protein encoded by SEQ ID Nos: 15, 22, or 26, classified in class 436, subclass 506.

The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups I-IV include isolated nucleic acids, isolated cancer associated antigens, antibodies, and vaccines comprising eukaryotic cells. Each product represents separate and distinct chemical compositions comprising distinct molecular entities which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Furthermore, the products are classified differently and would require different searches in the literature and or sequence databases.

The inventions of Groups V-XIV are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. For example, Groups V-VII and XIII-XIV are drawn to diagnosing and or screening for the presence of cancer, all of which entail screening for independent and or distinct products (i.e. DNA, protein, autoantibodies, immune cell complexes) that requires the use of different reagents employed in chemically distinct method steps that require the detection or consideration of distinctly different response variables. These methods further differ from the methods for monitoring a cancerous condition (Groups VIII-XII) as the objectives and critera for monitioring patients with a cancerous condition are independent and distinct from those subjects who have not yet been diagnosed with a cancerous disease.

The invention of Group I and the method of Groups V and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially

different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the nucleic acid products as claimed can be used in materially different processes such as affinity chromatography, methods of screening for cancer, or methods for monitoring a cancerous condition.

The invention of Group II and the method of Group VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the cancer associated antigen products as claimed can be used in materially different processes such as affinity chromatography.

The invention of Group IV and the method of Groups VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody products as claimed can be used in materially different processes such as affinity chromatography.

The invention of Group I-IV and the methods of Groups VII, IX, X-XI, and XIII-XIV are not at all related because the products of Groups I-IV are not used in any of the methods of Groups VII, IX, X-XI, and XIII-XIV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

April 22, 2004

GARY NICKOL
PRIMARY EXAMINER